

Office Action Summary

Application No.

10/826,919

Applicant(s)

DEITERS ET AL.

Examiner

KAGNEW H. GEBREYESUS

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-54, 56-59 and 62-64 is/are pending in the application.
- 4a) Of the above claim(s) 62 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 52 is/are allowed.
- 6) ☒ Claim(s) 53, 54, 56-59, 63 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/02/2009
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 2/6/09
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's reply dated August 29, 2008 in response to the Office Action requirement mailed on March 27, 2008 is acknowledged. Claim 55 is cancelled. Applicants have amended claims 53-54, 56-59. Applicants have added new claims 62-64. Applicants have elected the ORS species of SEQ ID NO: 48 in the previous Office Action. However new claim 62 comprising non-elected subject matter was added. This claim is withdrawn from further consideration because it comprises non-elected subject matter. Claims 52-54, 56-59, 63-64 are present for examination.

Objections and rejections not reiterated from the previous Office Action are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-54, 56-59, 63-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification teaches a method of using the ORS of SEQ ID NO: 48 that can be aminoacylated with para-azido-L-phenylalanine. However the claims are directed to the use of a genus of ORS molecules consisting not only of SEQ ID NO: 48-53 but also

any conservative variants of SEQ ID NO: 48-53. However no correlation between the structure of these 'sought for' variants and function is disclosed in the specification.

Furthermore the specification defines "conservative variant of a sequence" as any sequence that functions similarly to the structure it is similar to.

In paragraph [0084] Conservative variant: is defined as "conservative variant" refers to a translation component, e.g., a conservative variant O-tRNA or a conservative variant O-RS, that functionally performs like the component from which the conservative variant is based, e.g., an O-tRNA or O-RS, but has variations in the sequence. For example, an O-RS will aminoacylate a complementary O-tRNA or a conservative variant O-tRNA with an unnatural amino acid, although the O-tRNA and the conservative variant O-tRNA do not have the same sequence. The conservative variant can have, e.g., one variation, two variations, three variations, four variations, or five or more variations in sequence, as long as the conservative variant is complementary to the corresponding O-tRNA or O-RS.

Thus a conservative variant can have a sequence variation from an ORS that aminoacylates with either p-azido-L-phenylalanine or p-propargyloxyphenylalanine while being capable of aminoacylating with either unnatural amino acid. However claims 53-54, 56-59, 63-64 now encompass methods that utilize a genus of ORS to produce a protein comprising the above unnatural amino acids without disclosing the correlation of said function with any specific structure or conserved common structural motif.

While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." In the instant case the recited genus of ORS encompass species widely variant with respect to their structures, which include all ORS sequences that aminoacylate with a p-

propargyloxyphenylalanine or p-azido-L-phenylalanine but also variants of these ORS molecules.

While the specification teaches that ORS molecules with specific sequences able to aminoacylate with specific unnatural amino acids can be identified and such sequences have common sequence alterations at specific sites, the instant claims encompass any "conservative variants" of such sequences (see definition of conservative variants in the specification).

Furthermore the disclosure of SEQ ID NO: 48-53 is insufficient to be representative of the attributes and features of all species encompassed by the claimed sequence variants because minor variations within the sequence of any ORS molecule can have a profound effect on it's function (both activity and specificity to amino acids). However the specification does not disclose variants of functional ORS molecules that retain function.

Thus a method of using ORS sequences that comprises variants of functional molecules without specifying where these variations occur is encompassed. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Given this lack of description of representative species encompassed by the genus of the claim, claims 53-54, 56-59, 63-64 remain rejected under 35 U.S.C. 112, first paragraph since the specification fails to sufficiently describe the claimed invention

in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 103

Claim 53-56, 58 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al US 6,927,042 (priority claimed Jan. 16, 2003 **in IDS**) in view of Wang et al (Bioconjugation by Copper(I)-Catalyzed Azide-Alkyne [3+2] Cycloaddition **in IDS**) further in view of Chin et al (Addition of *p*-azido-L-phenylalanine to the genetic code of *Escherichia coli*, J. Am. Chem. Soc. 2002, vol. 124, 9026-9027, published on the Web on 07/11/2002 **in IDS**). This rejection is withdrawn following the amendments to the claims.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 52-59 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 52-59 of copending Application No. 10/561,121. (PG US 2006/0246509 A1). This is a provisional double patenting rejection since the conflicting

claims have not in fact been patented. Applicants point to the cancellation of claims 52-59 in Application No. 10/561,121. Therefore this rejection is withdrawn.

Claim 52 was provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 123 of copending Application No. 10/825,867 (PG US/2005/0009049 A1). Applicants point to the cancellation of claims 123 therefore this rejection is withdrawn.

Furthermore Applicants have expressed the fact that claim 123 in application 11/978,223 (erroneously referred to as application 10/978,243) may present a double patenting over claims that use SEQ ID NO: 48 and have expressed the fact that they will amend claim 123 to remove SEQ ID NO: 48 from application 11/978,223. Applicant's effort to clarify matters that could raise double patenting issue is greatly appreciated.

Conclusion: Claims 52 is allowable.

This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee of \$510.00.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection,

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whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAGNEW H. GEBREYESUS PhD whose telephone number is (571)272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kagnew H Gebreyesus/
Examiner, Art Unit 1656
2/10/2009

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657